



SIGACHI INDUSTRIES LIMITED

CIN : L24110TG1989PLC009497

To,

Date: May 07, 2025

The Manager BSE Limited P. J. Towers, Dalal Street Mumbai-400001 (BSE Scrip Code: 543389)	The Manager, National Stock Exchange of India Limited, Exchange Plaza, Bandra Kurla Complex, Bandra (E), Mumbai- 400051. (NSE Symbol: SIGACHI)
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Dear Sir/Madam,

Sub: Press Release- Trimax Biosciences Pvt Ltd, A Sigachi Group Company has successfully achieved the Certificate of Suitability (CEP) for “Metformin Hydrochloride” from European Directorate

Sigachi Industries Limited (“Company”), a leading player in pharmaceutical industry is pleased to announce that Trimax Biosciences Pvt Ltd, A Sigachi Group Company has successfully achieved the Certificate of Suitability (CEP) for “Metformin Hydrochloride” from European Directorate for the Quality of Medicines & Health Care (“EDQM”).

A press release to this extent is enclosed for your information and records.

Thanking you.

Yours Faithfully,
For Sigachi Industries Limited

Vivek Kumar
Company Secretary & Compliance Officer



Registered Office

#229/1 & 90, 2nd Floor, Kalyan’s Tulsiram Chambers, Madinaguda, Hyderabad-49, Telangana State, India.
Customer Service +91 40 40114874-76, E-mail: info@sigachi.com, URL: www.sigachi.com

Corporate Office

Plot No. G57/2, Industrial Park, Sultanpur, Hyderabad, Sangareddy (Dist), Telangana - 502319.
Tel No.: +91-8455-242055 / 56 / 57, E-mail: enquiry@sigachi.com, URL: www.sigachi.com



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Sigachi Industries Limited is pleased to announce that Trimax Biosciences Pvt Ltd, A Sigachi Group Company has successfully achieved the Certificate of Suitability (CEP) for “Metformin Hydrochloride” from European Directorate for the Quality of Medicines & Health Care (“EDQM”). This milestone paves the way for Trimax to export this crucial Active Pharmaceutical Ingredient (API) to Europe and other CEP-accepting markets, further strengthening Sigachi’s presence in highly regulated pharmaceutical markets.

Wednesday, 7th May 2025: Sigachi Industries Limited, a leading player in pharmaceutical industry has received the Certificate of Suitability (CEP) for Metformin Hydrochloride from European Directorate for the Quality of Medicines & Health Care (EDQM) on 5th May 2025. This certification reaffirms Sigachi’s commitment to stringent quality standards, regulatory compliance, and global market readiness.

- Metformin Hydrochloride, a widely used first-line therapy for type 2 diabetes management, is expected to grow to USD 386.91 million by 2030, with a compound annual growth rate (CAGR) of roughly 4.7% over the forecast period.
- The U.S. Food and Drug Administration (USFDA) has approved multiple Metformin-based FDCs, including Glucovance (glibenclamide + metformin), Actoplus Met (pioglitazone + metformin), Janumet (sitagliptin + metformin), Kombiglyze XR (saxagliptin + metformin), Jentaduetto (linagliptin + metformin), Oseni (alogliptin + pioglitazone), Invokamet (canagliflozin + metformin), and Xigduo XR (dapagliflozin + metformin). These approvals highlight the widespread acceptance and significance of Metformin-based therapies in diabetes treatment.
- The CEP certification for Metformin Hydrochloride aligns with the company’s strategy to penetrate stringently regulated markets, reinforcing Sigachi’s capability to meet EU standards for safety, efficacy, and GMP compliance.

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Commenting on this development, Mr. Amit Raj Sinha, Managing Director and CEO of Sigachi Industries Limited stated

“This achievement aligns perfectly with our vision of expanding into highly regulated markets and strengthen our position in the global pharmaceutical industry. With the rising demand for Metformin-based therapies, Sigachi is committed to leveraging its R&D expertise and state-of-the-art facilities to deliver pharmaceutical solutions that meet international standards and address the dynamic needs of the healthcare sector.”

For further information on the Company, please visit www.sigachi.com

About Trimax Biosciences Pvt Ltd

Founded on May 11, 2010, Trimax Bio Sciences Private Limited is a proud subsidiary of Sigachi Industries Limited, specializing in the development and manufacture of active pharmaceutical ingredients (APIs), intermediates, and advanced intermediates. Located in Raichur, Karnataka, our state-of-the-art facility is designed to meet the highest industry standards, complying with USFDA, cGMP, EMEA, and WHO-GMP guidelines.

At Trimax, we are committed to delivering excellence in every product we create. Our USFDA-approved facility focuses on producing critical and advanced intermediates that play a pivotal role in modern healthcare solutions. By combining cutting-edge technology with rigorous quality assurance, we aim to address the evolving needs of the global pharmaceutical market. With a strong emphasis on innovation, quality, and compliance, Trimax Bio Sciences is more than a manufacturer—we’re a reliable partner in advancing global health.

For further information, please contact:

Mr. Chaitanya Rapol
Senior Manager – Marketing, Branding and Communications
Sigachi Industries Limited
Email: chaitanya.rapol@sigachi.com



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Forward-Looking Statements

This press release contains forward-looking statements, including but not limited to statements relating to the expected business impact of the Certificate of Suitability (CEP) for Metformin Hydrochloride, market expansion plans, and future strategic goals. These statements are based on current expectations, projections, and assumptions and are subject to known and unknown risks, uncertainties, and other factors that could cause actual outcomes to differ materially from those expressed or implied.

Key factors that could cause actual outcomes to differ include, but are not limited to, changes in regulatory environments, competitive pressures, global market dynamics, raw material availability, and manufacturing or operational challenges.

Sigachi Industries Limited assumes no obligation to publicly update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise, except as required under applicable law.

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